UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

DONALD MILLER, Plaintiff, vs. **DePUY ORTHOPAEDICS, INC., and DePUY INC., and DEPUY INTERNATIONAL LIMITED, and JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES INC. and JOHNSON & JOHNSON INTERNATIONAL,** Defendants.	Case No. 2:11-cv-640 Judge: **COMPLAINT** **JURY TRIAL DEMANDED**

COMES NOW Plaintiff DONALD MILLER, by and through undersigned counsel, and alleges as follows:

INTRODUCTION

1. This is a civil action brought on behalf of Plaintiff for personal injuries and economic damages sustained as a direct and proximate result of the negligent and wrongful conduct of Defendants DEPUY ORTHOPAEDICS, INC.; DEPUY INC.; DEPUY INTERNATIONAL LIMITED; JOHNSON & JOHNSON SERVICES, INC.; JOHNSON & JOHNSON, INC. and JOHNSON & JOHNSON INTERNATIONAL in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of an artificial hip, sold as the Pinnacle System.

2. At all times material hereto, the Pinnacle System was designed, developed,

manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by DePuy Orthopaedics, Inc. and, Johnson & Johnson and/or their subsidiaries.

PARTIES AND JURISDICTION

3. Jurisdiction is proper in this Court pursuant to 28 U.S.C.A. §1332. All parties to this action are of diverse citizenship. The amount in controversy exceeds $75,000.00 exclusive of interests and costs.

4. Plaintiff is a citizen and resident of the State of Ohio.

5. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district, as the Defendants collectively have marketed, sold, distributed, or otherwise distributed Pinnacle Hip Systems with the Southern District of Ohio

6. At all material times to this lawsuit, Defendant was authorized to do business within the State of Ohio and derived substantial revenues from products designed and sold in Ohio and within the Plaintiff's District.

7. On information and belief, Defendant DEPUY ORTHOPAEDICS, INC is a corporation formed in the State of Indiana with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC is, and was at all relevant times herein, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Pinnacle Hip system. At all relevant times, Defendant DEPUY ORTHOPAEDICS, INC conducted regular and sustained business in Ohio by selling and distributing its products in Ohio.

8. On information and belief, Defendant DEPUY, INC is a corporation formed in the State of Indiana with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY, INC is, and was at all relevant times herein, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying,

selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Pinnacle Hip system. At all relevant times, Defendant DEPUY, INC conducted regular and sustained business in Ohio by selling and distributing its products in Ohio

9. On information and belief, Defendant DEPUY INTERNATIONAL LIMITED is a corporation formed in the State of Indiana with its principal place of business located at St. Anthonys Road, Beeston, Leeds West Yorkshire, LS11 8DT, United Kingdom. Defendant DEPUY INTERNATIONAL LIMITED is, and was at all relevant times herein, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Pinnacle Hip system. At all relevant times, Defendant DEPUY INTERNATIONAL LIMITED conducted regular and sustained business in Ohio by selling and distributing its products in Ohio.

10. On information and belief, Defendant JOHNSON & JOHNSON SERVICES, INC is a corporation formed in the State of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON SERVICES, INC is, and was at all relevant times herein, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Pinnacle Hip System. At all relevant times, Defendant JOHNSON & JOHNSON SERVICES, INC conducted regular and sustained business in Ohio by selling and distributing its products in Ohio.

11. On information and belief, Defendant JOHNSON & JOHNSON, INC is a corporation formed in the State of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON, INC is, and was at all relevant times herein, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing,

and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Pinnacle Hip System. At all relevant times, Defendant JOHNSON & JOHNSON SERVICES, INC conducted regular and sustained business in Ohio by selling and distributing its products in Ohio.

12. On information and belief, Defendant JOHNSON & JOHNSON INTERNATIONAL is a corporation formed in the State of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON INTERNATIONAL is, and was at all relevant times herein, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Pinnacle Hip System. At all relevant times, Defendant JOHNSON & JOHNSON INTERNATIONAL conducted regular and sustained business in Ohio by selling and distributing its products in Ohio.

13. Defendants DEPUY ORTHOPAEDICS, INC, DEPUY, INC, DEPUY INTERNATIONAL LIMITED, JOHNSON & JOHNSON SERVICES, INC, JOHNSON & JOHNSON, INC, and JOHNSON & JOHNSON INTERNATIONAL will be collectively referred to in this Complaint as the "Defendants."

14. Plaintiff DONALD MILLER shall herein be referred to as "Plaintiff."

15. Upon information and belief, at all times, the Defendants transacted, solicited, and conducted business in the State of Ohio and derived substantial revenue from such business.

FACTUAL BACKGROUND

A. DePuy's Pinnacle Hip Is Unsafe And Has Not Been Adequately Tested

16. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur

and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

17. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

18. The Pinnacle Hip has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular liner. The design of the Pinnacle Hip was not sufficiently tested by the Defendants, and it was never approved by the FDA as being safe or effective for the products' intended purpose.

19. The Pinnacle Hip is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

20. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Hip, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

21. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when

relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

22. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

23. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval.

24. In addition, a medical device marketed *after* the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (*i.e.*, a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then clear the new device for sale in the United States.

25. The MDA does not require an FDA determination that the device is in fact, substantially equivalent to a grandfathered device.

26. Instead of assuring the safety of the Pinnacle Hip through clinical trials, DePuy sought to market its Pinnacle Hip without conducting any clinical trials by obtaining FDA approval under section 510(k). To that end, Defendants submitted a section 510(k) premarket notification of intent to market the Pinnacle Hip.

27. By telling the FDA that the Pinnacle Hip's design was "substantially equivalent" to other hip products on the market, DePuy was able to avoid the safety review required for premarket approval under FDA regulations including clinical trials.

28. The FDA cleared the Pinnacle Hip for sale by means of the abbreviated 510(k) process and consequently, the FDA did not require the Pinnacle Hip to undergo clinical trials.

29. The 510(k) notification for the Pinnacle Hip includes only Defendant DePuy's assertion that it believes the DePuy Pinnacle Hip to be substantially equivalent to devices that themselves had never been reviewed for safety and effectiveness.

30. Significantly, unlike the premarket approval process, the 510(k) notification process does not call for scrutiny – or even clinical testing – of a device's safety and effectiveness.

31. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness. This point is forcefully underscored by the FDA's letter to DePuy, which says nothing about the safety and effectiveness of the Pinnacle Hip; finds only that the device was "substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976"; and concludes by stressing that the agency's determination of substantial equivalence "does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies."

32. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the Pinnacle Hip's safety and effectiveness, but rather only a determination of equivalence to devices that themselves underwent no safety and effectiveness review.

33. While most hip replacements use a polyethylene ***plastic*** acetabular liner, DePuy's Pinnacle Hip has a critical difference: it uses a ***metal*** acetabular liner. By using a metal acetabular liner and a metal femoral ball, the Pinnacle Hip forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design for the Pinnacle Hip, hundreds of patients—including Plaintiff Donald Miller—have been and/or will be forced to undergo surgeries to replace the failed hip implants.

34. Plaintiff believes that the Pinnacle Hip suffers from a similar design or manufacturing defect that forced DePuy to recall over 93,000 metal-on-metal ASR and ASR XL hip implants. While the exact nature of the common defect is still being investigated, Plaintiff believes that both hip implants suffer from one or more similar design or manufacturing defects

that cause excessive amounts of cobalt and chromium to wear from the surface of the acetabular insert or from the femoral head. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

35. Due to a host of problems, including early failure, these metal-on-metal total hip replacement systems were largely abandoned decades ago and replaced by implants composed of metal on polyethylene or other synthetic components.

36. However, in an effort to increase revenues, hip implant manufacturers began in the late 1990s to aggressively market hip implant surgery to a growing younger and more active demographic. As a part of this marketing effort, defendants resurrected the previously abandoned metal-on-metal total hip replacement systems, marketing them as much more durable and longer performing. In what was a complete triumph of marketing over medicine, defendants advertised the previously abandoned and decades old metal-on-metal hip implant design as a new, "second generation" device. Unfortunately, these "second generation" metal-on-metal hip implants (including the Pinnacle metal-on-metal total hip replacement system which is the subject of this lawsuit) pose the same unreasonable dangers and health risks that caused the manufacturers to abandon the "first generation" decades before.

B. DePuy Should Have Recalled The Pinnacle Hip Years Ago; Over 1,300 Adverse Events Related To The Pinnacle Hip Have Been Reported

37. It wasn't long after DePuy launched the Pinnacle Hip that reports of failures began flooding into DePuy. For example, on May 4, 2002, DePuy received a complaint that a patient had to undergo a surgery to remove and replace the hip implant because the liner disassociated with the cup. DePuy closed its investigation of this complaint, finding that "corrective action is not indicated." Two weeks later, on May 17, 2002, DePuy received another report that another patient had to undergo surgery to remove and replace a defective hip implant

because the acetabular cup had loosened. Again, DePuy closed its investigation of this complaint, finding that "corrective action is not indicated."

38. DePuy would go on to receive hundreds of similar complaints reporting that the Pinnacle Hip had failed due to premature loosening of the acetabular cup and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component.

39. By the time DePuy sold the Pinnacle Hip to Donald Miller in October, 2008, DePuy had received hundreds of complaints related to the Pinnacle Hip. Consequently, DePuy was fully aware that the Pinnacle Hip was defective and that hundreds of patients already had been injured by that defect. Based on this information, DePuy should have recalled the Pinnacle Hip before it was sold to Mr. Miller. At minimum, DePuy should have stopped selling the defective implant when it became aware that it had catastrophically failed in patients.

40. By the end of 2008, DePuy had received more than 430 reports and by the end of 2009, that number had skyrocketed to almost 750. To date, DePuy has received an astonishing ***1,300 reports*** associated with Pinnacle Hips.

41. Despite its knowledge that the Pinnacle Hip had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, DePuy continued to sell the defective hip implant. In so doing, DePuy actively concealed the known defect from doctors and patients—including Mr. Miller and his doctor—and misrepresented that that the Pinnacle Hip was a safe and effective medical device.

42. DePuy's reason to conceal the defect in its Pinnacle Hip is clear. In 2009 alone, DePuy brought in more than $5.4 billion in sales. Hip implant sales are critically important to DePuy's parent company, Johnson & Johnson, and DePuy is one of Johnson & Johnson's most profitable business groups. In 2008, DePuy was faced with a critical defect in one of its hip implant systems. The last thing DePuy wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety,

DePuy decided that it would not issue an embarrassing recall when it learned of the defects with its Pinnacle Hip. Moreover, motivated by greed rather than patient safety, DePuy did not even stop selling the Pinnacle Hip. Instead, it continued to manufacture the hip implants and it continued to sell them to unsuspecting patients. To this day, DePuy continues to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

C. Mr. Miller's Pinnacle Hip Was Defective And Failed, Forcing Him To Undergo An Additional Painful And Risky Surgery

43. On October 16, 2008, Mr. Miller underwent a surgical procedure to implant the Pinnacle Hip in his right hip. He was 57 years old. By this time, Defendants had already received reports that the Pinnacle Hip had failed and it knew that the product was defective, but Defendants refused to disclose that information to Mr. Miller, his physicians, or the public.

44. Shortly after surgery, Mr. Miller began experiencing pain in his right hip and groin. This went on for months and included swelling, deformity and loosening of the right hip implant. As a result of his defective Pinnacle Hip Mr. Miller endured constant pain, a decrease in his quality of life, revision surgery and other serious health problems.

45. On April 18, 2011, Mr. Miller underwent a painful, complex and risky surgery (known as a "revision surgery") to remove and replace the metal-on-metal components that had failed. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications. Mr. Miller's surgery revealed damage to muscle and tissue as a result of the metal-on-metal DePuy device.

46. Also, having to go a through revision surgery will subject Mr. Miller to much greater risks of future complications than he had before the revision surgeries. For example, several studies have found that just one revision surgery causes a much higher risk of dislocation

compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and his colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost ***four times more likely*** to suffer from a hip dislocation than those who have not. (Phillips CB, *et al*. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

47. As a direct and proximate result of the failure of his defective Pinnacle Hip and the Defendants' wrongful conduct, Mr. Miller sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Mr. Miller has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the jurisdictional minimum of this court.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DEFECTIVE MANUFACTURING

48. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

49. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Pinnacle Hip System.

50. The Pinnacle Hip System manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury.

51. As a direct and proximate result of Plaintiff's use of the Pinnacle Hip System as

manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

52. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY—DEFECTIVE MANUFACTURING-- PURSUANT TO OHIO REVISED CODE SECTION 2307.74

53. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

54. Plaintiff is a "claimant" as defined at Ohio Rev. Code §§ 2307.71(A)(1)(a) in that Plaintiff is making a "product liability claim," as defined by Ohio Rev. Code §§ 2307.72(A)(13) for damages caused by Plaintiff's use of the Pinnacle Hip System, an "ethical medical device" as defined by R.C. 2307.71(A)(5), manufactured, designed, sold, distributed, supplied and/or placed this product in the stream of commerce by Defendants who are "manufacturers" as defined by Ohio Rev. Code §§ 2307.71(A)(9) and/or "suppliers" as defined by Ohio Rev. Code §§ 2307.71(A)(15).

55. The Pinnacle Hip System manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk of injury, regardless of whether Defendants exercised all possible care in its manufacture or construction.

56. The foregoing acts and/or omissions of Defendants were in violation of Ohio Rev. Code §2307.74 since the Pinnacle Hip System Acetabular System manufactured by Defendants was defective in manufacture or construction.

57. As a direct and proximate result of Plaintiff's use of the Pinnacle Hip System as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

58. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DESIGN DEFECT

59. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

60. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Pinnacle Hip System.

61. The Pinnacle Hip System manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect and it failed to comply with

federal requirements for these medical devices.

62. The Pinnacle Hip System that was implanted into the Plaintiff had not been materially altered or modified prior to the implantation of the device.

63. The foreseeable risks associated with the design or formulation of the Pinnacle Hip System, include, but are not limited to, the fact that the design or formulation of Pinnacle Hip System is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner and/or it failed to comply with federal requirements.

64. As a direct and proximate result of Plaintiff's use of the Pinnacle Hip System as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

65. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DESIGN DEFECT PURSUANT TO OHIO REVISED CODE SECTION 2307.75

66. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

67. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Pinnacle Hip System.

68. The Pinnacle Hip System manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the

foreseeable risks of the product, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with its design or formulation, as defined by Ohio Rev. Code §§ 2307.75(C), or it was more dangerous than an ordinary consumer would expect.

69. As set forth elsewhere in this Complaint, the foreseeable risks of the Pinnacle Hip System, as defined at Ohio Rev. Code §§ 2307.75(B)(1) – (5), include but are not limited to the following:

a. the unreasonable risk of the product failing early and causing extreme pain and suffering and the need for explantation of the device, as defined at Ohio Rev. Code §§ 2307.75(B)(1);

b. the unlikely awareness to the users of the Pinnacle Hip System of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of the Pinnacle Hip System, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(2);

c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as a hip implantation device, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(3);

d. the design or formulation of the Pinnacle Hip System produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective hip implantation devices not as prone to early failure, as defined at Ohio Rev. Code §§ 2307.75(B)(4);

e. the design or formulation of the Pinnacle Hip System produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would

expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using the Pinnacle Hip System for a hip replacement, all as defined at Ohio Rev. Code §§ 2307.75(B)(5).

70. The Defendants failed to provide an adequate warning as to the risks of the Pinnacle Hip System and for this reason Defendants may not claim that the Pinnacle Hip System is not defective in design or formulation, though it is unsafe, as contemplated under Ohio Rev. Code §§ 2307.75(D).

71. As a direct and proximate result of Plaintiff's use of the Pinnacle Hip System as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

72. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

FIFTH CAUSE OF ACTION
STRICT PRODUCTS LIABILTY – DEFECT DUE TO INADEQUATE WARNING

73. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

74. The Pinnacle Hip System manufactured and supplied by Defendants was

defective due to inadequate warning or instruction because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks as follows:

a. The device contained insufficient warnings to alert consumers and their prescribing physicians that the Pinnacle Hip System posed an unreasonably high risk of failure once implanted;

b. Defendants' promotional materials, labeling and instructional materials that accompanied the Pinnacle Hip System were inadequate and misleading to consumers and their prescribing physicians;

c. Even after defendant's received notice from reputable medical sources prior to the sale of the device to the plaintiff, that the device presented an inordinately high risk of failure and harm to the consumer, defendant knowingly and deliberately failed to warn the public, including Plaintiff and Plaintiff's prescribing physician(s), of the serious risk of injury and failure occasioned by the defects in the device;

d. The Pinnacle Hip System did not conform to the representations made by Defendants concerning the device; and

e. Defendant's representations concerning the Pinnacle Hip System did not conform to applicable federal requirements.

75. The Defendants, as manufacturers of the Pinnacle Hip System, are held to the level of knowledge of an expert in the field of that type of prosthetic device, and had a duty to warn its consumers and prescribing physicians of the dangers associated with the device and

failed to do so.

76. The Pinnacle Hip System manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm, as set forth herein, from the use of the Pinnacle Hip System, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury as set forth herein.

77. As a direct and proximate result of Plaintiff's use of the Pinnacle Hip System as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff was implanted with the Pinnacle Hip System and suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

78. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY—DEFECTIVE DUE TO INADEQUATE WARNING--PURSUANT TO OHIO REVISED CODE SECTION 2307.76

79. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

80. The Pinnacle Hip System manufactured and supplied by Defendants was defective due to inadequate warning or instruction because Defendants knew or should have known that the medical device created significant risks of serious bodily harm and early failure

of the device and they failed to adequately warn consumers and/or their health care providers of such risks, as defined at Ohio Rev. Code §§ 2307.76(A)(1)(a) – (b).

81. In addition to, or in the alternative, the Pinnacle Hip System manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and early failure of the device f, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and that it could fail early, as defined at Ohio Rev. Code §§2307.76(A)(2)(a) – (b).

82. The risks of Pinnacle Hip System were not open and obvious, as defined at Ohio Rev. Code §§ 2307.76(B).

83. As a direct and proximate result of Plaintiff's use and implantation of the Pinnacle Hip System as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

84. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

SEVENTH CAUSE OF ACTION
STRICT PRODUCTS LIABILTY DUE TO NON CONFORMANCE WITH REPRESENTATIONS

85. Plaintiff incorporates by reference each and every paragraph of this Complaint as

if fully set forth herein and further alleges as follows:

86. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of orthopedic devices including the Pinnacle Hip System and made representations regarding the character or quality of this device.

87. Pinnacle Hip System manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product and/or with applicable federal requirements.

88. Plaintiff justifiably relied upon Defendants' representations regarding the Pinnacle Hip System when Plaintiff selected this DePuy orthopedic product to be used in surgery.

89. As a direct and proximate result of Plaintiff's use of the Pinnacle Hip System and his reliance on Defendants' representations regarding the character and quality of the Pinnacle Hip System and/or the failure to comply with federal requirements, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

90. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages

EIGHTH CAUSE OF ACTION
STRICT PRODUCTS LIABILTY DUE TO NON CONFORMANCE WITH REPRESENTATIONS PURSUANT TO R.C. 2307.77

91. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

92. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of the Pinnacle Hip System and made representations regarding the character or quality of this device.

93. The Pinnacle Hip System manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product, as defined at Ohio Rev. Code §§ 2307.77.

94. Plaintiff justifiably relied upon Defendants' representations regarding the Pinnacle Hip System when it was implanted into the Plaintiff.

95. Upon information and belief, the warnings provided to physicians who choose to use the Pinnacle Hip System, including the physician(s) that chose to implant the Pinnacle Hip System into Plaintiff, were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

96. As a direct and proximate result of Plaintiff's use of the Pinnacle Hip System as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

97. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

NINTH CAUSE OF ACTION
NEGLIGENCE

98. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of the Pinnacle Hip Implant Devices, including a duty to insure that the Pinnacle Hip Implant Devices did not pose a significantly increased risk of adverse events.

99. Defendants failed to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of the Pinnacle Hip Implant Devices. Defendants knew or should have know that the Pinnacle Hip Implant Devices could fail early in patients therefore giving rise to pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, and therefore was not safe for use by Plaintiff.

100. Despite the fact that Defendants knew or should have known that the Pinnacle Hip Implant Devices could fail early in patients therefore giving rise to pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, Defendants continued to market the Pinnacle Hip Implant Devices as a safe and effective hip replacement systems.

101. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered significant damages, including but not limited to physical injury, pain and suffering, and the need for further surgery to replace the faulty device, further treatment and will continue to suffer such damages in the future.

102. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive

damages.

TENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

103. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

104. Defendants expressly warranted that the Pinnacle Hip System was a safe and effective orthopedic device for those patients requiring a hip replacement.

105. The Pinnacle Hip System manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to Plaintiff when used as recommended and directed.

106. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

ELEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

107. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

108. At the time Defendants designed, manufactured, marketed, sold, and distributed the Pinnacle Hip System for use by Plaintiff, Defendants knew of the use for which the Pinnacle Hip System was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling and marketing complied with all applicable federal requirements.

109. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Pinnacle Hip System was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters, including that it was in compliance with

all federal requirements.

110. Contrary to such implied warranty, the Pinnacle Hip System was not of merchantable quality or safe for its intended use, because the product was unreasonably dangerous and defective as described above and/or it failed to comply with federal requirements.

111. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

TWELFTH CAUSE OF ACTION
NEGLIGENT REPRESENTATION AND FRAUD

112. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

113. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product, the Pinnacle Hip System created an unreasonable risk of serious bodily injury and/or that it failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet Defendants negligently misrepresented to Plaintiff and/or Plaintiff's physician(s) that its device was safe and met all applicable design and manufacturing requirements.

114. Plaintiff reasonably relied to Plaintiff's detriment upon Defendants' fraudulent actions and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff reasonably relied upon Defendants' representations to Plaintiff and/or Plaintiff's health care provider(s) that the Pinnacle Hip System was safe for use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

115. As a direct and proximate result of Defendants' fraudulent and/or negligent

actions and omissions and/or its failure to disclose its violations of federal requirements applicable the Pinnacle Hip System, Plaintiff used the Pinnacle Hip System and suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

116. Defendants' actions and omissions as identified in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

THIRTEENTH CAUSE OF ACTION
UNJUST ENRICHMENT

117. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

118. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase and implementation of the Pinnacle Hip System by Plaintiff.

119. Defendants have voluntarily accepted and retained those profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the quality, nature, or fitness that had been represented by Defendants, or that Plaintiff, as a reasonable consumer, expected to receive.

120. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

FIFTEENTH CAUSE OF ACTION
PUNITIVE DAMAGES

121. Plaintiff hereby incorporates by reference all allegations contained in the preceding paragraphs, as though fully set forth herein.

122. At all times material hereto, the Defendants knew or should have known that the Pinnacle Hip System was inherently more dangerous and prone to failure than other hip replacement devices.

123. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety and efficacy of the Pinnacle Hip System.

124. Defendants' misrepresentation included intentionally withholding material information from the medical community and the public, including Plaintiff, regarding the safety of the Pinnacle Hip System.

125. Notwithstanding the foregoing, Defendants continued to aggressively market the Pinnacle Hip System to consumers, including Plaintiff, without disclosing the aforesaid problems and failure rate.

126. The Defendants knew of Pinnacle Hip System's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by the device.

127. Defendants fraudulently, intentionally, and/or recklessly concealed and failed to disclose to the public, including Plaintiff, the dangers and higher failure rate of the Pinnacle Hip System in order to ensure continued and increased sales.

128. Defendants' intentional and/or reckless failure to disclose information deprived

Plaintiff of the necessary information to enable Plaintiff to weigh the true risk of using the Pinnacle Hip System against its benefits.

129. The aforesaid conduct of Defendants in the license, approval process, design, manufacturing, assembly, packaging, warning, marketing, advertising, promotion, distribution and sale of the Pinnacle Hip System was fraudulent, knowing misconduct, willful and/or conduct undertaken to recklessly and with conscious disregard for the safety of Plaintiff such as to constitute despicable conduct, and oppression, fraud and malice, and at all time relevant, such conduct was ratified by the corporate Defendants herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish and set an example to Defendants, and to deter them from similar conduct in the future.

130. Plaintiff seeks actual and punitive damages from the Defendants as alleged herein pursuant to all appropriate state statutes and common law. The injuries and damages alleged herein are permanent and will continue into the future.

PRESERVATION CLAIMS

131. Plaintiff hereby incorporates by reference all allegations contained in the preceding paragraphs, as though fully set forth herein.

132. Many States have recently enacted tort reform statutes with "exclusive remedy" provisions. Courts have yet to determine whether these exclusive remedy provisions eliminate or supercede, to any extent, state common law claims. If during the pendency of this action this court makes any such determination, Plaintiff hereby specifically makes claim to and preserves any State claim based upon any exclusive remedy provision, under any state law this court may apply, to the extent not already alleged above.

133. To the extent that Defendant(s) may claim that one or more of Plaintiff's

claims are barred by the applicable statute of limitations, Plaintiff asserts that the statute of limitations is and has been tolled by Plaintiff's discovery that her injury(ies) was/were caused by Defendants' defective product and failure to properly and adequately warn of the products' risks, all as more fully set forth in this Complaint, after the injury sustained by Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, DONALD MILLER, prays for the following relief:

A. Trial by jury;

B. Judgment in favor of Plaintiff and against all Defendants, for damages in such amounts as may be proven at trial;

C. Compensation for non-economic losses, including, but not limited to medical expenses, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

D. Punitive and/or exemplary damages in such amounts as may be proven at trial;

E. Restitution and disgorgement of all revenue that Defendants have obtained through the manufacture, marketing, sale and administration of the Pinnacle Hip Implant Devices;

F. Attorneys' fees and costs;

G. Pre- and post-judgment interest; and

H. Any and all further relief, both legal and equitable, that the court may deem just and proper.

Respectfully submitted,

/s/ Richard W. Schulte
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JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.